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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,573	02/08/2001	Etienne Regulier	017753-137	5075

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Norman H Stepno
Burns Doane Swerker & Mathis
PO Box 1404
Alexandria, VA 22313-1404

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,573

Applicant(s)

REGULIER ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,11-15,19,20,24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,11-15,19,20 and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/03 has been entered.

Claims 1, 7, 11-15, 19, 20, and 24-32 are pending.

Applicants' traversal, the amendment to claims 1, 7, 19, and 32, and the cancellation of claims 2-6, 8-10, 16-18, and 21-23 in paper filed on 11/20/03 are acknowledged and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 11, 12, 13, 19, 20, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 filed on 11/20/03 introduces new subject matter into the application. The application and the originally filed claims as a whole are directed to a composition intended for the implementation of a cytotoxic treatment in mammals, comprising: (i) a nucleic acid sequence encoding all or part of an MIP chemokine, (ii) at least one nucleic acid sequence encoding IL-2, said nucleic acid sequence being placed under the control of elements required for the expression in a host cell of said mammal.

The original specification and claims do not disclose, "wherein the IL-2 and MIP chemokine work together synergistically". The pages cited for support of the claimed invention do not provide support for the claimed invention. See Pages 29-32 in the examples and Figures 1-6. The specification recites, "We have now identified novel cytotoxic compositions in which the various constituents are chosen so to obtain a synergistic effect of their respective activities and improved properties of said constituents (Page 3, lines 17-20). However, the specification does not describe what is a synergistic effect and does not specifically point out what cytotoxic composition produces a synergistic effect. In addition, the working examples do not disclose a composition comprising a nucleic acid sequence encoding an MIP chemokine and a nucleic acid sequence encoding IL-2, wherein the IL-2 and MIP chemokine work together synergistically. It is apparent that the applicants at the time the invention was made did not intend or contemplate the claimed invention as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the claimed invention, where IL-2 and MIP chemokine working together synergistically, at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 7, 11, 12, 13, 19, 20, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the compound" on line 8. There is insufficient antecedent basis for this limitation in the claim. Claims 7, 11, 12, 13, 19, 20, 24, and 25 are dependent from claim 1 and are also indefinite.

Claims 1, 7, 11, 12, 13, 19, 20, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship is: IL-2 and MIP chemokine work together synergistically to do what.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear what "comprising capable of being transformed into a cytotoxic molecule by a polypeptide having at least cytotoxic activity" means.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 11-15, 19, 20, 24, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bournnell et al. (US Patent 6,287,557, EFD 2/21/96) taken with Hobart et al. (US Patent 5,147,055, EFD 3/14/97) and Nakashima et al. (Pharm. Res. 13:1896-1901, 1996).

Bournnell teaches virus vectors encoding nucleotide sequences expressing immunomodulating proteins including cytokines and chemokines and combinations thereof (col. 6, lines 55-67), such as IL-2, MIP1 α , and MIP1 β (col. 7, lines 1-11) for cancer immunotherapy,

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wherein each of the sequences are placed under control of a known viral promoter or a mammalian specific promoter (col. 9, lines 45-51). Bournnell further teaches making and using a vector comprising two or more nucleotide sequences or a mixture of two vectors containing at least one gene encoding a different immunomodulator product (col. 8, lines 50-55).

Furthermore, Bournnell teaches a method of using the vector for cancer immunotherapy in an animal by direct or indirect administration (col. 11, lines 8-67). The vector can be a mutant DNA or RNA virus, e.g., adenovirus, poxvirus (col. 5, lines 49-55). The vectors used in the method taught by Bournnell are in pharmaceutically acceptable formulas. However, Bournnell does not specifically teach making and using a composition comprising a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding an MIP chemokine for reducing tumors in an animal.

However, at the time the invention was made, Hobart teaches a method of treating a solid tumor in an animal comprising introducing a vector comprising IL-2 into the solid tumors (col. 4, lines 33-41, col. 4, line 66- col. 5, and col. 33, line 33 to col. 36, line 37).

In addition, at the time the invention was made, Nakashima teaches reducing tumorigenicities in mice inoculated with adenocarcinoma cells (page 1896) using a vector comprising a nucleotide sequence encoding MIP1 α . Nakashima teaches that MIP α has potential value for cancer gene therapy.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the inventions was made to combine the teaching of Bournnell taken with Hobart and Nakashima to make and use a composition comprising a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding an MIP chemokine. One of ordinary skill in the art would have been

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motivated to combine the teachings because a composition comprising a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding MIP1 α were well known to one of ordinary skill in the art for reducing tumors in an animal. Therefore, it would be obvious to one of ordinary skill in the art to make the composition.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Boursnell taken with Hobart and Nakashima to make and use a composition comprising at least two nucleotide sequences encoding IL-2 and a nucleotide sequence encoding an MIP chemokine. One of ordinary skill in the art would have been motivated to combine the teachings because Boursnell teaches making a combination of nucleotide sequence encoding IL-2 and a nucleotide sequence encoding MIP1 α . Therefore, it would be obvious to one of ordinary skill in the art to make the composition comprising at least two nucleic acid sequences encoding IL-2 and a nucleic acid sequence encoding an MIP chemokine to increase reduction of tumor cells.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Boursnell taken with Hobart and Nakashima to make a composition comprising a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding an MIP chemokine, wherein the composition is inserted into a recombinant adenovirus vector. One of ordinary skill in the art would have been motivated to combine the teachings because recombinant adenoviral vectors comprising an anti-tumor gene were well known to one of ordinary skill in the art for reducing tumors in an animal. Therefore, it would be obvious to one of ordinary skill in the art to make the adenoviral vector to reduce tumor cells.

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It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the inventions was made to combine the teaching of Boursnell taken with Hobart and Nakashima to make and use a composition comprising a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding an MIP chemokine for treating a tumor in an animal. One of ordinary skill in the art would have been motivated to combine the teachings because a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding MIP1 α were well known to one of ordinary skill in the art for reducing tumors in an animal. Therefore, is would been obvious to one of ordinary skill in the art to use the composition to reduce tumors in an animal and achieve a reasonable expectation of success.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the inventions was made to combine the teaching of Boursnell taken with Hobart and Nakashima to make and use a composition comprising a nucleotide sequence encoding IL-2 and a nucleotide sequence encoding an MIP chemokine and a pharmaceutically acceptable carrier. One of ordinary skill in the art would have been motivated to combine the teachings because the composition and a pharmaceutically acceptable carrier well known to one of ordinary skill in the art for reducing tumors in an animal as taught by Boursnell taken with Hobart and Nakashima. Therefore, is would been obvious to one of ordinary skill in the art to make the composition with a pharmaceutically acceptable carrier to reduce tumor cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicants' arguments filed 11/20/03 have been fully considered but they are not persuasive. See pages 8-10.

In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, MPEP 2144.06 states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). This is the case here. At the time the invention was made, a vector comprising a nucleotide sequence encoding a MIP chemokine or a vector comprising a nucleotide sequence encoding IL-2 were known to treat a tumor in an animal. In addition, Boursnell teaches the reasonable expectation of success for making a composition comprising a nucleotide sequence encoding multiple immunomodulating proteins.

Furthermore, the applicants are reminded that the motivation for combining the teachings of the prior art may be different from applicants' motivation to make the disclosed compositions. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App.

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& Inter. 1985). The office has provided motivation for making a composition comprising a nucleic acid sequence encoding MIP and a nucleotide sequence encoding IL-2.

With respect to the argument that the added limitation overcomes the 103(a) rejection, the argument is not found persuasive because claims 14, 15, 26 and 31 do not recite the limitation.

Furthermore, with respect to claims 1, 2, 7, 11, 12, 13, 19, 20, 24, and 25, which recite the newly added functional language drawn to “wherein the IL-2 and MIP chemokine work together synergistically,” it is noted that a “wherein the IL-2 and MIP chemokine work together synergistically” has been rejected under 35 U.S.C. 112 first paragraph, new matter, and 112 second paragraph, see above. In addition, **the applicants’ claims are product claims, not method claims, except for claim 24.** The asserted unexpected property of the composition is directed to using the composition in a particular method and is not commensurate in scope with the product claims. MPEP 2111.02 states, .. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.” *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136, USPQ 458, 459 (CCPA 1963). MPEP further states, “Where the claimed and prior art products are identical or substantially identical in structure or compositions, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation **or obviousness** has been established. MPEP 2112.01 states:

In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case

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can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In *re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

Also, reliance upon inherency is not improper even though a rejection is based on Section 103 instead of 102. *In re Skoner*, 517 F.2d 947, 186 USPQ 80 (CCPA 1975).

Claims 1, 11, 13, 15, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boursnell et al. (US Patent 6,287,557, EFD 2/21/96) taken with Hobart et al. (US Patent 5,147,055, EFD 3/14/97) and Nakashima et al. (Pharm. Res. 13:1896-1901, 1996) in further view of Bruder et al. (US Patent 6,440,944, EFD 10/16/98).

The rejection of the base claims 1, 11, 13, 15, and 26 under 35 U.S.C. 103(a) are applied here as indicated above, by Boursnell taken with Hobart and Nakashima. However, Boursnell taken with Hobart and Nakashima do not specifically teach making a replication defective adenoviral vector, wherein said adenoviral vector is deleted in the E1 region, or E1 and E4, or E1 and E3, or E1, E3, and E4.

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However, at the time the invention was made, replication defective adenoviral vectors were well known in the art for gene delivery because they are superior vehicle for transferring genetic material to a wide variety of cells and represent a safe choice of gene transfer. Bruder teaches that a variety of recombinant adenoviral vectors are known in the art for gene delivery (col. 1, lines 34-55). Bruder teaches an adenoviral vector with a gene of interest inserted into the E1 region of the adenovirus. Furthermore, Bruder teaches multiply deficient adenoviral vectors that are deficient in E1, E3 and E4. One of ordinary skill in the art understands that a recombinant adenoviral vector is replication defective because genes essential for adenovirus replication are deleted.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to make and use a replication defective adenoviral vector in the composition taught by Boursnell taken with Hobart and Nakashima. One of ordinary skill in the art would have been motivated to use a replication defective adenoviral vector because they are superior vehicle for transferring genetic material to a wide variety of cells and represent a safe choice of gene transfer. In addition, one of ordinary skill in the art would have been motivated to use a multiply deficient adenoviral vector (E1-; E1-E4-; and E-1, E3-) to abolish expression of the adenoviral proteins (E1, E3, and/or E4) to improve the delivery of exogenous nucleic acid sequences to an animal.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicants' arguments filed 11/20/03 have been fully considered but they are not persuasive. See pages 11 and 12.

In response to applicants' arguments against the references individually (e.g. Bruder), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. Bruder teaches that replication defective adenoviral vectors were well known in the art, at the time the invention was filed, for gene delivery because they are superior vehicle for transferring genetic material to a wide variety of cells and represent a safe choice of gene transfer. Thus, one skilled in the art would have been motivated to use a replication defective adenoviral vector in the claimed invention.

Furthermore, with respect to the argument for the added limitation (see page 12), the argument is not found persuasive for the same reasons as set forth under the response to applicants' argument against the prior 103(a) rejection.

Claims 14, 15, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bournnell et al. (US Patent 6,287,557, EFD 2/21/96) taken with Hobart et al. (US Patent 5,147,055, EFD 3/14/97) and Nakashima et al. (Pharm. Res. 13:1896-1901, 1996) in further view of Gruber (US Patent 6,410,326, EFD 6/7/1995).

The rejection of the base claims 14, 15, and 31 under 35 U.S.C. 103(a) are applied here as indicated above, by Bournnell taken with Hobart and Nakashima. However, Bournnell taken

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with Hobart and Nakashima do not specifically teach making a poxvirus vector selected from the group consisting of vaccinia virus, MVA, and canary pox.

However, at the time the invention was made, vaccinia virus were well known in the art for expressing heterologous proteins at high levels as taught by Gruber (col. 7, line 65, col.8, line 26).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to make and use vaccinia virus in the composition taught by Bournnell taken with Hobart and Nakashima. One of ordinary skill in the art would have been motivated to make and use a vaccinia viral vector because vaccinia virus vectors were well known in the art for expressing heterologous proteins at high levels.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicants' arguments filed 11/20/03 have been fully considered but they are not persuasive. See pages 12 and 13.

In response to applicants' arguments against the references individually (e.g., Gruber), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. vaccinia virus was well known in the art for expressing heterologous proteins at high levels as taught by Gruber. Thus, one skilled in the art would have been motivated to use a vaccinia virus in the claimed invention.

With respect to applicants' argument that vaccinia vectors would not work *in vivo*, the argument is not found persuasive because the argument is not supported by any evidence of record. See MPEP § 716.01(c). Furthermore, even if the argument were supported, the argument would be moot because the claims are directed to **a product** and not **a method of using the product**. See *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136, USPQ 458, 459 (CCPA 1963).

Furthermore, the argument is not found persuasive for the same reasons as set forth under the response to applicants' argument against the previous 103(a) rejections.

Response to Arguments

Applicant's arguments, filed 11/20/03, with respect to the claim objection have been fully considered and are persuasive. The objection of claims 7, 19, and 32 has been withdrawn because of the amendment to the claims. See pages 7-8.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

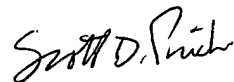
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

A handwritten signature in black ink, appearing to read "Scott D. Pribe".

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER